

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **Confirmation No. 5291**
Mie TAKAHASHI et al. : Attorney Docket No. 2001_1464A
Serial No. 09/937,730 : Group Art Unit 1641
Filed January 8, 2002 : Examiner Gary W. Counts
CHROMATOGRAPHY MEDIUM AND
ITS MANUFACTURING METHOD : **Mail Stop: RCE**

RESPONSE FILED CONCURRENTLY WITH RCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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ACCOUNT NO. 23-0975

Sir:

The following remarks are submitted together with a Request for Continued Examination, and are responsive to the Advisory Action dated September 4, 2008, and the Final Rejection of April 22, 2008, the time for responding thereto being extended for three months in accordance with the Petition for Extension of Time submitted herewith. Applicants submit the following remarks in support of the patentability of the presently claimed invention over the disclosures of the references relied upon by the Examiner in rejecting the claims. Further and favorable reconsideration is respectfully requested in view of these remarks.

Summary of Discussion with Examiner

Initially, Applicants wish to thank the Examiner for participating in a telephone conversation with Applicants' representative on August 21, 2008. During this discussion, the Examiner indicated that he would be issuing an Advisory Action, and he expressed his positions, which are now of record in the Advisory Action of September 4, 2008. The Examiner recommended providing evidence demonstrating the unexpected results achieved by Applicants' invention, when compared to the Chu reference. The Examiner indicated that such comparisons

should be submitted together with a Request for Continued Examination (RCE).

Applicants sincerely appreciate the Examiner's helpful comments, and in order to expedite allowance of the application, have heeded the Examiner's advice. The remarks and suggested comparison are set forth in detail below.

Patentability Arguments

The patentability of the present invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Rejections Under 35 U.S.C. § 103(a)

The rejection of claims 5, 12, 27, 31, 41, 45, 53 and 60 under 35 U.S.C. § 103(a) as being unpatentable over Chu (U.S. 6,284,194) in view of Nanbu et al. (U.S. 6,130,055) or Uenoyama et al. (U.S. 5,856,117); as well as the rejection of claim 49 under 35 U.S.C. § 103(a) as being unpatentable over Chu in view of Nanbu et al. or Uenoyama et al. and further in view of Iwata et al. (U.S. 5,912,139), are respectfully traversed.

Examiner's Position

In the Advisory Action, the Examiner states that Applicants' previously asserted arguments are not found to be persuasive. Specifically, the Examiner asserts that the surfactants of the cited references can be considered equivalent, because they come from the same family of surfactants (non-ionic surfactants). The Examiner asserts that one of ordinary skill in the art would have a reasonable expectation of success incorporating surfactants such as those taught by Nanbu et al. and Uenoyama et al. into the method of Chu.

Additionally, the Examiner states that claim 5 does not require the medium to be in dry form, but merely states that the surface active agent is solidified when dried.

Applicants' Arguments

Initially, Applicants note that preservation stability is neither disclosed nor suggested in any of Chu, Nanbu et al. nor Uenoyama et al. Thus, Applicants assert that improved preservation stability is not taught or suggested by any combination of these cited references.

Throughout the prosecution history of this application, Applicants have presented objective assertions that preservation stability is an important factor in this technical field. Specifically, please see the remarks set forth in the Response filed March 10, 2008. Additionally, Applicants have presented objective assertions regarding the physical distinctions between the surfactants of Applicants' invention, and the surfactants of the primary reference (Chu). Specifically, please see the remarks set forth in the Response After Final Rejection filed July 18, 2008.

Additionally, in accordance with the Examiner's suggestion, Applicants discuss below a comparison of Applicants' invention and the teachings of Chu.

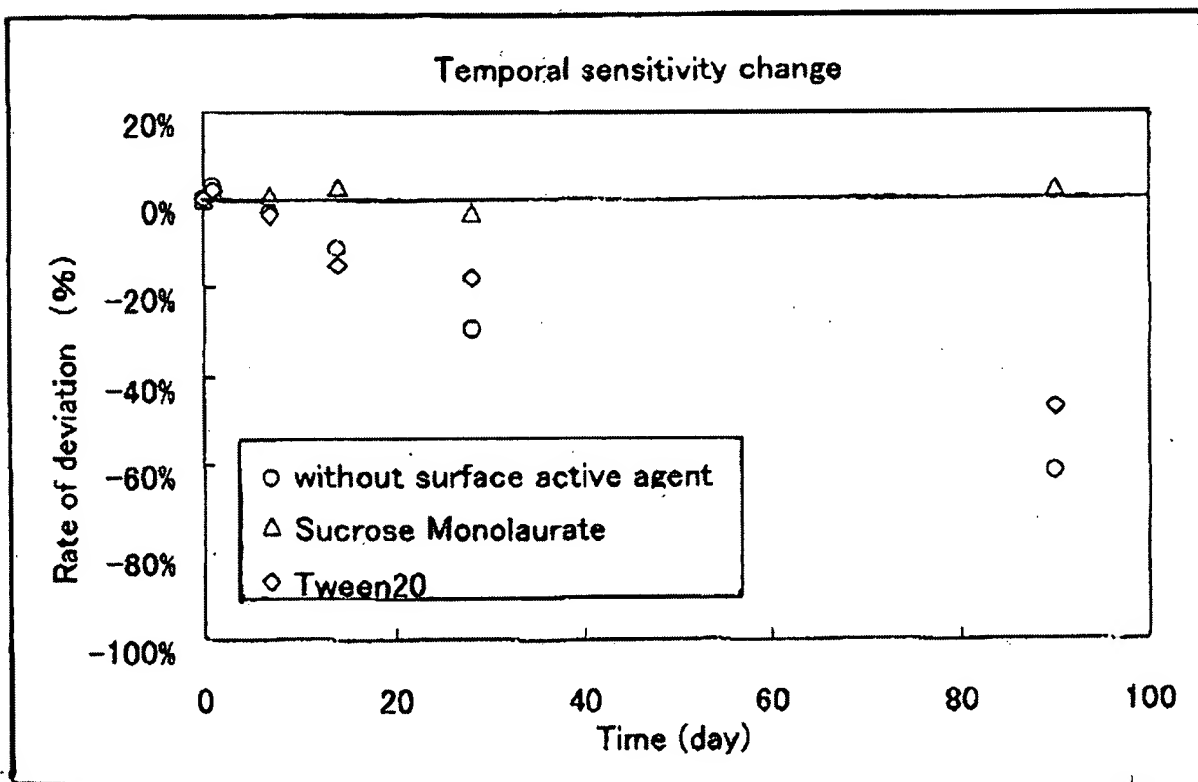
First, a chromatography specimen was produced in accordance with Example 1 of Applicants' specification. Specifically, in accordance with Example 1 (pages 33-34) of Applicants' specification, an anti-hCG- β antibody solution, obtained by dilution with a phosphate buffer solution to perform the concentration adjustment, was produced for an immunochromatography specimen. This antibody solution was applied on the nitrocellulose film by adopting a solution discharge device. Thereby, an antibody immobilization line for detection was obtained on the nitrocellulose film. After the nitrocellulose film was dried, this nitrocellulose film was immersed in a Tris-HCl buffer solution including 1% skim milk and gently shaken for 30 minutes. After 30 minutes, the nitrocellulose film was moved into a Tris-HCl buffer solution tank, gently shaken for 10 minutes, and then gently shaken in another Tris-HCl buffer solution tank for another 10 minutes, so as to wash the nitrocellulose film. After washing twice, the nitrocellulose film was immersed in a Tris-HCl buffer solution including 0.05% Sucrose Monolaurate (made by Dojindo Laboratories), shaken for 10 minutes, then taken out from the solution tank, and dried at room temperature.

Another test specimen was similarly produced, except that Tween20 (Polyoxyethylene Sorbitan Monolaurate) was used instead of 0.05% Sucrose Monolaurate. [This specimen is

based upon a surfactant taught by the Chu reference.]

The test specimens were then stored in an aluminum seal, which also includes a molecular sieve as a desiccant, in a reservoir with a constant temperature of 25°C. After 1 day, 7 days, 14 days, 28 days, and 90 days of storage, a measurement for each specimen was performed by applying blood plasma including hCG of 0, 100, 1000, and 10000U/l (which were adjusted for each specimen) to the test specimens, as in the Examples of the Applicants' specification. By setting the sensitivity at the time of setting a regression formula as 0, the total concentration mean of the change in sensitivity from the beginning is plotted on a graph, shown below.

The graph compares the test specimen treated with 0.05% Sucrose Monolaurate, the test specimen which was treated with 0.05% Tween20 in place of the 0.05% Sucrose Monolaurate, and a test specimen where no treatment is performed with surface active agent.



As shown in the above graph, the test specimen which was not treated with a surface active agent provides sensitivity which begins to gradually decrease on the 7th day, and has a sensitivity reduction of up to about 60% on the 90th day. Additionally, the test specimen treated with Tween20, which does not comprise sugar structure in a hydrophilic part and is surface active agent in liquid form at normal temperature and normal pressure, similarly indicates a decrease in sensitivity, i.e., about -4%, on the 7th day. Further, the test specimen treated with Tween 20 has a sensitivity reduction of about -50% on the 90th day. On the contrary, the test specimen in accordance with Applicants' claims does not have a decrease in sensitivity. The poor results of the other two specimens arise from multiple factors, such as a debasement of permeability caused by the test specimen structure in this technical field using the permeability of test body, alteration and deactivation of specific protein caused by the mixing of liquid materials, and an increase in the background caused by the labeled-substance nonspecific adsorption which results from the above-mentioned matters.

It is clear from the above discussion that the test specimen in accordance with Applicants' claims has superior and unexpected results when compared to the test specimen treated with a surfactant according to Chu. At the Examiner's suggestion, Applicants have clearly demonstrated that a surfactant according to Applicants' invention is unexpectedly superior to a surfactant taught by Chu. Accordingly, the Examiner's general assertion that all non-ionic surfactants can be considered equivalent is untenable.

In view of the above comparison, as well as the Applicants' arguments previously asserted during the prosecution of this application, Applicants respectfully assert that the pending claims are patentable over the cited combinations of references. Accordingly, the rejections of record are no longer tenable, and should be withdrawn.

Conclusion

Therefore, in view of the remarks submitted above, as well as those previously asserted during the prosecution of this application, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, the Examiner is respectfully requested to contact the undersigned by telephone in order to resolve such issues.

Respectfully submitted,

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By: 2008.10.22 15:27:18 -04'00'

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